image

AF/1615

F-7125

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant	:	Stefan BRACHT
Serial No.	:	09/937,534
Filed	:	September 26, 2001
For	:	TRANSDERMAL THERAPEUTIC SYSTEM WITH NICOTINE AND ADDITION OF MONOTERPENE KETONES
Group Art Unit	:	1615
Examiner	:	Micah Paul Young

Certificate of Mailing Under 37 CFR 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to COMMISSIONER FOR PATENTS, P.O. Box 1450, Alexandria, VA 22313-1450 on January 20, 2004.

C. Bruce Hamburg (Name)

(Signature)

APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is an appeal from the final rejection of claims 1-3, 6, 8 and 14-16 dated July 21, 2003. This brief is submitted in triplicate. Please charge the $330 appeal brief fee to Deposit Account No. 10-1250. Also, charge any fee deficiency or credit any excess payment to Deposit Account No. 10-1250.

01/26/2004 SLUANG1 00000004 101250 09937534
01 FC:1402 330.00 DA

REAL PARTY IN INTEREST

This application is assigned to LTS Lohmann Therapie-Systeme AG, which is the sole real party in interest.

RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences known to the appellant or the appellant's legal representatives which will directly affect or be directly affected by or have a bearing on the Board's decision in the present appeal.

STATUS OF CLAIMS

The claims appealed are all the pending claims, namely, claims 1-3, 6, 8 and 14-16. Claims 4, 5, 7 and 9-13 have been canceled.

STATUS OF AMENDMENTS

No amendment has been filed subsequent to the final rejection of July 21, 2003.

SUMMARY OF THE INVENTION

Prior art embodiments of a transdermal therapeutic system (hereinafter "TTS") to aid in the cessation of smoking, commonly known as a "nicotine patch,"

are comprised of a nicotine-containing layer or zone. Such a TTS has an unpleasant odor due to the nicotine content (e.g., p. 1, lines 2-9). According to the invention, an additive comprising at least one monoterpene ketone in the nicotine-containing layer or zone in a proportion of 0.1 to 5.0%-wt, preferably 0.5 to 2%-wt is highly effective in masking the nicotine odor (e.g., p. 3, lines 9-12; p. 7, lines 8-10). The invention is defined by claims to the TTS containing monoterpene ketone (claims 1-3, 14 and 15) and claims to the process of masking the unpleasant odor of nicotine in the TTS by adding monoterpene ketone to the nicotine-containing layer or zone (claims 6, 8 and 16)

ISSUES

The issues presented for review are:

(1) whether claims 1-3, 14 and 15 are unpatentable under 35 U.S.C. 103(a) over Baker et al (USP 5,362,496) in view of Yamaguchi et al (USP 5,820,877) and Majeti (USP 5,599,554); and

(2) whether claims 6, 8 and 16 are unpatentable under 35 U.S.C. 103(a) over the same combination of references as in Issue No. 1 but "all in view of" Brisken et al (USP 3,559,655) and DeFoney et al (USP 4,039,653).

GROUPING OF CLAIMS

For each ground of rejection which appellant contests herein which applies to more than one claim, such additional claims, to the extent the subject matter thereof is separately identified and argued, stand or fall separately.

ARGUMENT

ISSUE NO. 1

The rejection of claims 1-3, 14 and 15 under 35 U.S.C. 103(a) as being unpatentable over Baker et al (USP 5,362,496) in view of Yamaguchi et al (USP 5,820,877) and Majeti (USP 5,599,554) is erroneous.

The final rejection misrepresents the disclosure Baker et al, the primary reference. This is best understood by first summarizing what Baker et al actually discloses.

Baker et al discloses, as a treatment method and system for smoking cessation, a combination of transdermal administration of nicotine and transmucosal administration of nicotine (col. 1, lines 6-13). The transdermal administration is effected by a TTS (patch). See, e.g., col. 8, line 6- col. 15, last line. There is no disclosure of any TTS which contains a monoterpene ketone. The transmucosal administration is effected by an "oral drug dosage form" (e.g., col. 1, lines 9-15). The substantial listings of oral administration forms in Baker et al does not include

any TTS because, by definition, a TTS is applied to the skin, not inserted in one's mouth.

A preferred oral administration form is a lozenge (e.g., col. 5, lines 11-22). Baker et al discloses "the lozenge may contain a flavorant, for example, a candy taste, such as chocolate, orange, vanilla, and the like; or other flavor, such as aniseed, eucalyptus, 1-menthol, carvone, amethole, and the like, to mask the taste of nicotine." (Col. 20, lines 25-31.)

In order to construct a rejection the Examiner has conflated disparate Baker et al teachings relating only to transdermal administration and only to transmucosal administration to present a four sentence characterization of Baker et al of which three of the sentences misrepresent Baker et al as follows:

(1) "Baker et al teaches a transdermal or transmucosal formulation comprising a backing layer and an adhesive matrix layer." Baker et al, however, does not teach a transmucosal formulation comprising a backing layer and an adhesive matrix layer.

(2) "The transdermal formulation includes nicotine as a drug and essential oils." Only lonzenges of Baker et al, however, may contain an essential oil (or, more to the point, carvone).

(3) "The reference states the formulation can be made into both transmucosal and transdermal formulations." Presumably, "the formulation" refers to the formulation of (2), but that formulation is only for lozenges.

The secondary references do not rehabilitate the rejection. The Examiner concedes that Yamaguchi et al neither discloses nor makes obvious the inclusion of a monoterpene ketone in a nicotine patch. In the Examiner's words, "The patch is however silent to the inclusion of monoterpene ketones." The Examiner implicitly makes the same concession with respect to Majeti et al.

Moreover, since the inclusion of a monoterpene in a nicotine patch would not have been obvious, the determination of optimum proportions of monoterpene and preferred monoterpenes for such inclusion would have been all the more unobvious.

ISSUE NO. 2

The rejection of claims 6, 8 and 16 under 35 U.S.C. 103(a) as unpatentable over the same combination of references as in Issue No. 1, but "all in view of" Brisken et al and DeFoney et al is erroneous.

To the same extent that nicotine patches containing a monoterpene ketone would not have been obvious to one or ordinary skill in the art, so, too the process step of including a monoterpene in a nicotine patch would not have been obvious.

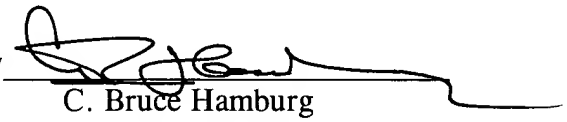
Therefore, the comments relating to Baker et al, Yamaguchi et al and Majeti under the "Issue No. 1" heading are incorporated in the present discussion by reference. This leaves DeFoney et al and Brisken.

De Foney et al relates to an oral deodorant. That disclosure is no more relevant to the present invention than would be mint-flavored mouthwash.

Brisken et al relates to smoking products which do not contain tobacco and, hence, do not contain nicotine, the absence of nicotine being expressly stated (e.g., col. 1, lines 12-21). How Brisken et al can be considered pertinent to an invention relating to nicotine is beyond imagination.

Respectfully submitted,

JORDAN AND HAMBURG LLP

By 

C. Bruce Hamburg
Reg. No. 22,389
Attorney for Applicants

Jordan and Hamburg LLP
122 East 42nd Street
New York, New York 10168
(212) 986-2340

APPENDIX

LISTING OF APPEALED CLAIMS

1. Transdermal therapeutic system comprising a backing layer, at least one nicotine-containing layer or zone, and an additive comprising at least one monoterpene ketone, wherein the content of at least one monoterpene ketone in the nicotine-containing layer or zone is 0.1 to 5.0%-wt of the weight of the layer or zone.

2. Transdermal therapeutic system according to claim 1, wherein the monoterpene ketone is selected from the group consisting of carvone, dihydrocarvone, menthone, isopulegone, isomenthone, neomenthone, neoisomenthone and piperitone.

3. Transdermal therapeutic system according to claim 2, wherein the monoterpene ketone is a pure enantiomer thereof or a mixture of enantiomers thereof.

6. Process for masking an unpleasant smell, caused by the presence of nicotine, comprising adding to a nicotine-containing layer or zone of a nicotine-

containing transdermal therapeutic system, 0.1 to 5.0%-wt, based on the weight of the layer or zone, of at least one monoterpene ketone.

8. Process according to claim 6, wherein the monoterpene ketone is selected from the group consisting of carvone, dihydrocarvone, menthone, isopulegone, isomenthone, neomenthone, neoisomenthone and piperitone.

14. Transdermal therapeutic system according to claim 1, wherein the nicotine-containing layer or zone has pressure-sensitive adhesive properties and is covered by a removable protective layer.

15. Transdermal therapeutic system according to claim 1, wherein the content of the at least one monoterpene ketone in the nicotine-containing layer or zone is 0.5- 2%-wt of the weight of the layer or zone.

16. Process according to claim 6, wherein the at least one mototerpene ketone is added to the nicotine - containing layer or zone in a quantity constituting 0.5-2% wt of said layer or zone.

F-7125

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant	:	Stefan BRACHT
Serial No.	:	09/937,534
Filed	:	September 26, 2001
For	:	TRANSDERMAL THERAPEUTIC SYSTEM WITH NICOTINE AND ADDITION OF MONOTERPENE KETONES
Group Art Unit	:	1615
Examiner	:	Micah Paul Young

Certificate of Mailing Under 37 CFR 1.8

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to COMMISSIONER FOR PATENTS, P.O. Box 1450, Alexandria, VA 22313-1450 on January 20, 2004.

C. Bruce Hamburg
(Name)

(Signature)

APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is an appeal from the final rejection of claims 1-3, 6, 8 and 14-16 dated July 21, 2003. This brief is submitted in triplicate. Please charge the $330 appeal brief fee to Deposit Account No. 10-1250. Also, charge any fee deficiency or credit any excess payment to Deposit Account No. 10-1250.

REAL PARTY IN INTEREST

This application is assigned to LTS Lohmann Therapie-Systeme AG, which is the sole real party in interest.

RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences known to the appellant or the appellant's legal representatives which will directly affect or be directly affected by or have a bearing on the Board's decision in the present appeal.

STATUS OF CLAIMS

The claims appealed are all the pending claims, namely, claims 1-3, 6, 8 and 14-16. Claims 4, 5, 7 and 9-13 have been canceled.

STATUS OF AMENDMENTS

No amendment has been filed subsequent to the final rejection of July 21, 2003.

SUMMARY OF THE INVENTION

Prior art embodiments of a transdermal therapeutic system (hereinafter "TTS") to aid in the cessation of smoking, commonly known as a "nicotine patch,"

are comprised of a nicotine-containing layer or zone. Such a TTS has an unpleasant odor due to the nicotine content (e.g., p. 1, lines 2-9). According to the invention, an additive comprising at least one monoterpene ketone in the nicotine-containing layer or zone in a proportion of 0.1 to 5.0%-wt, preferably 0.5 to 2%-wt is highly effective in masking the nicotine odor (e.g., p. 3, lines 9-12; p. 7, lines 8-10). The invention is defined by claims to the TTS containing monoterpene ketone (claims 1-3, 14 and 15) and claims to the process of masking the unpleasant odor of nicotine in the TTS by adding monoterpene ketone to the nicotine-containing layer or zone (claims 6, 8 and 16)

ISSUES

The issues presented for review are:

(1) whether claims 1-3, 14 and 15 are unpatentable under 35 U.S.C. 103(a) over Baker et al (USP 5,362,496) in view of Yamaguchi et al (USP 5,820,877) and Majeti (USP 5,599,554); and

(2) whether claims 6, 8 and 16 are unpatentable under 35 U.S.C. 103(a) over the same combination of references as in Issue No. 1 but "all in view of" Brisken et al (USP 3,559,655) and DeFoney et al (USP 4,039,653).

GROUPING OF CLAIMS

For each ground of rejection which appellant contests herein which applies to more than one claim, such additional claims, to the extent the subject matter thereof is separately identified and argued, stand or fall separately.

ARGUMENT

ISSUE NO. 1

The rejection of claims 1-3, 14 and 15 under 35 U.S.C. 103(a) as being unpatentable over Baker et al (USP 5,362,496) in view of Yamaguchi et al (USP 5,820,877) and Majeti (USP 5,599,554) is erroneous.

The final rejection misrepresents the disclosure Baker et al, the primary reference. This is best understood by first summarizing what Baker et al actually discloses.

Baker et al discloses, as a treatment method and system for smoking cessation, a combination of transdermal administration of nicotine and transmucosal administration of nicotine (col. 1, lines 6-13). The transdermal administration is effected by a TTS (patch). See, e.g., col. 8, line 6- col. 15, last line. There is no disclosure of any TTS which contains a monoterpene ketone. The transmucosal administration is effected by an "oral drug dosage form" (e.g., col. 1, lines 9-15). The substantial listings of oral administration forms in Baker et al does not include

any TTS because, by definition, a TTS is applied to the skin, not inserted in one's mouth.

A preferred oral administration form is a lozenge (e.g., col. 5, lines 11-22). Baker et al discloses "the lozenge may contain a flavorant, for example, a candy taste, such as chocolate, orange, vanilla, and the like; or other flavor, such as aniseed, eucalyptus, 1-menthol, carvone, amethole, and the like, to mask the taste of nicotine." (Col. 20, lines 25-31.)

In order to construct a rejection the Examiner has conflated disparate Baker et al teachings relating only to transdermal administration and only to transmucosal administration to present a four sentence characterization of Baker et al of which three of the sentences misrepresent Baker et al as follows:

(1) "Baker et al teaches a transdermal or transmucosal formulation comprising a backing layer and an adhesive matrix layer." Baker et al, however, does not teach a transmucosal formulation comprising a backing layer and an adhesive matrix layer.

(2) "The transdermal formulation includes nicotine as a drug and essential oils." Only lonzenges of Baker et al, however, may contain an essential oil (or, more to the point, carvone).

(3) "The reference states the formulation can be made into both transmucosal and transdermal formulations." Presumably, "the formulation" refers to the formulation of (2), but that formulation is only for lozenges.

The secondary references do not rehabilitate the rejection. The Examiner concedes that Yamaguchi et al neither discloses nor makes obvious the inclusion of a monoterpene ketone in a nicotine patch. In the Examiner's words, "The patch is however silent to the inclusion of monoterpene ketones." The Examiner implicitly makes the same concession with respect to Majeti et al.

Moreover, since the inclusion of a monoterpene in a nicotine patch would not have been obvious, the determination of optimum proportions of monoterpene and preferred monoterpenes for such inclusion would have been all the more unobvious.

ISSUE NO. 2

The rejection of claims 6, 8 and 16 under 35 U.S.C. 103(a) as unpatentable over the same combination of references as in Issue No. 1, but "all in view of" Brisken et al and DeFoney et al is erroneous.

To the same extent that nicotine patches containing a monoterpene ketone would not have been obvious to one or ordinary skill in the art, so, too the process step of including a monoterpene in a nicotine patch would not have been obvious.

Therefore, the comments relating to Baker et al, Yamaguchi et al and Majeti under the "Issue No. 1" heading are incorporated in the present discussion by reference. This leaves DeFoney et al and Brisken.

De Foney et al relates to an oral deodorant. That disclosure is no more relevant to the present invention than would be mint-flavored mouthwash.

Brisken et al relates to smoking products which do not contain tobacco and, hence, do not contain nicotine, the absence of nicotine being expressly stated (e.g., col. 1, lines 12-21). How Brisken et al can be considered pertinent to an invention relating to nicotine is beyond imagination.

Respectfully submitted,

JORDAN AND HAMBURG LLP

By _____
C. Bruce Hamburg
Reg. No. 22,389
Attorney for Applicants

Jordan and Hamburg LLP
122 East 42nd Street
New York, New York 10168
(212) 986-2340

APPENDIX

LISTING OF APPEALED CLAIMS

1. Transdermal therapeutic system comprising a backing layer, at least one nicotine-containing layer or zone, and an additive comprising at least one monoterpene ketone, wherein the content of at least one monoterpene ketone in the nicotine-containing layer or zone is 0.1 to 5.0%-wt of the weight of the layer or zone.

2. Transdermal therapeutic system according to claim 1, wherein the monoterpene ketone is selected from the group consisting of carvone, dihydrocarvone, menthone, isopulegone, isomenthone, neomenthone, neoisomenthone and piperitone.

3. Transdermal therapeutic system according to claim 2, wherein the monoterpene ketone is a pure enantiomer thereof or a mixture of enantiomers thereof.

6. Process for masking an unpleasant smell, caused by the presence of nicotine, comprising adding to a nicotine-containing layer or zone of a nicotine-

containing transdermal therapeutic system, 0.1 to 5.0%-wt, based on the weight of the layer or zone, of at least one monoterpene ketone.

8. Process according to claim 6, wherein the monoterpene ketone is selected from the group consisting of carvone, dihydrocarvone, menthone, isopulegone, isomenthone, neomenthone, neoisomenthone and piperitone.

14. Transdermal therapeutic system according to claim 1, wherein the nicotine-containing layer or zone has pressure-sensitive adhesive properties and is covered by a removable protective layer.

15. Transdermal therapeutic system according to claim 1, wherein the content of the at least one monoterpene ketone in the nicotine-containing layer or zone is 0.5- 2%-wt of the weight of the layer or zone.

16. Process according to claim 6, wherein the at least one mototerpene ketone is added to the nicotine - containing layer or zone in a quantity constituting 0.5-2% wt of said layer or zone.